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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,112	10/21/2004	Noboru Tsuchimori	2007_0561	6413

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
12/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,112	TSUCHIMORI ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *6 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8-11-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed September 23, 2008 is acknowledged. New claims 11 and 12 are presented.

In the Response filed March 11, 2008 to a requirement for an Election of Species, Applicants elected the specie 1-acetyl -N-(3-{4-[4-(aminocarbonyl)benzyl)-1-piperidinyl}propyl)-N-(3-chloro-4-methylphenyl)-4-piperidinecarboxamide, which is also known as TAK 220. The subject matter presently under consideration are those methods and agents for the treatment of graft-versus host disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation comprising administering TAK 220. Claims 6 and 8 remain withdrawn from consideration by the Examiner, as directed to non-elected inventions, 37 CFR 1.142(b). Accordingly, claims 1-5, 7 and 9-12 are now under consideration.

An Information Disclosure Statement filed August 11, 2008 is further acknowledged and has been reviewed to the extent each reference is a proper citation on a U.S. patent.

A new Abstract is noted.

Those objections and/or rejections set forth in the last Office Action that are not herein reiterated are withdrawn. The following rejections constitute the only rejections that are presently applied to the instant claims.

Claim 5 was rejected under 35 U.S.C. 112, first paragraph, in the last Office Action because the specification, while being enabling for showing the preparation of various dosage forms and for the preparation of compounds having a CCR antagonist effect, does not enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to practice the invention commensurate in scope with these claims.

The present invention is broadly drawn to the treatment of graft-versus host disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation. As previously evidenced by The Merck Manual, the treatment for transplantation is still somewhat limited and unpredictable.

Applicants have deleted the term "preventing" from claim 5.

The instant specification, however, merely provides support for preparing those compounds characterized as CCR antagonists and compositions comprising such compounds. The disclosure also provides background material directed to the general state of the art. The disclosure is clearly not predictable for any treatment modality for any graft-versus host disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation in a mammal. There are no working examples to support any such methodologies

Absent reasonable *a prio*ri expectations of success for using a "CCR antagonist" to treat a particular rejection reaction, one skilled in the immunology art would have to test extensively the many CCR antagonists that are known in the art to discover which particular type of rejection reaction responds to a particular compound. Considering the state of the art, unpredictability of treatment and the total lack of support provided by the specification for the claimed methods - support that is commensurate in scope with the claims - one of ordinary skill in the immunology arts would be burdened with undue experimentation to treat heart, liver, kidney or bone marrow rejection reactions

comprising administering the instantly claimed "CCR antagonists." The rejection of record of claim 5 under 35 U.S.C. 112, first paragraph, is maintained, and presently extended to include new method claims 1, 3, 4 and 12,

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-5, 7 and 9-12 are rejected under 35 U.S.C. 102(e), as being anticipated by Miki et al., US 2006/0094877.

Miki teaches Compound X, which is 1-acetyl -N-(3-{4-[4-(aminocarbonyl)benzyl)-1-piperidinyl}propyl)-N-(3-chloro-4-methylphenyl)-4-piperidinecarboxamide for use in the treatment of graft-versus host disease. See page 9, paragraph [0067], and page 17, paragraph [0145]. As required by instant claim 7, a process for manufacturing an agent comprising a CCR antagonist with a pharmaceutically acceptable diluent is disclosed on page 16, paragraph [0141]. Agents comprising 1-acetyl -N-(3-{4-[4-(aminocarbonyl)benzyl)-1-piperidinyl}propyl)-N-(3-chloro-4-methylphenyl)-4-piperidinecarboxamide are described on page 16, paragraphs [0141].

Claims 1-4, 9 and 10 were rejected under 35 U.S.C. 102(e), as being anticipated by Imamura et al., U.S. Patent 6,562,978, in the last Office Action. It was asserted Imamura teaches the compound 1-acetyl -N-(3-{4-[4-(aminocarbonyl)benzyl)-1-

piperidinyl}propyl)-N-(3-chloro-4-methylphenyl)-4-piperidinecarboxamide, as in claim 2, column 232, and prepared as Example 376, column 202. Imamura teaches compositions comprising the recited compounds in column 32, line 60, to column 33, line 22, as well as in column 230, lines 47-67, to column 231, line 15.

Applicants argue the cited reference fails to disclose the use of the claimed compounds in the method of claim 5.

The original rejection was solely directed to claims drawn to "agents." Claim 5, a method of use claim, was not included in this rejection.

Subsequent to the amendment to the claims, in which claims that were originally composition claims are now method of use claims, i.e., claims 1, 3 and 4, the rejection of record of claims 2, 9, 10 under 35 U.S.C. 102(e), as being anticipated by Imamura et al., U.S. Patent 6,562,978, is maintained and the rejection is presently extended to include new compound claim 11.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 26, 2008 /Phyllis G. Spivack/

Primary Examiner, Art Unit 1614